DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#21

Re: Bepadin/Vascor
Docket No. 91E-0106

APR 1 0 1991

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. Re. 30,577 filed by Riom Laboratories C.E.R.M. under the patent term extension provisions of 35 U.S.C. 156. The human drug products claimed by the patent are Bepadin/Vascor (bepridil hydrochloride) New Drug Applications (NDA) 19-001 (Bepadin) and 19-002 (Vascor).

A review of the Food and Drug Administration's official records indicates that these products were subject to a regulatory review period before commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that they represent the first permitted commercial marketing or use of the active ingredient.

Both NDAs were approved on December 28, 1990, which makes the submission of the patent term extension application on February 22, 1991 timely within the meaning of 35 U.S.C. 156 (d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d) we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Kevin B. Clarke, Esq.
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